In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 11-398V December 7, 2012 Not to be Published

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CANDICE JOHNSON,	*	
	*	
Petitioner,	*	
,	*	
v.	*	Failure to prosecute; Gardasil;
	*	Menactra; seizures
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
**********	*****	
Candice Johnson, Dolton, IL, for petit	ioner (pro se).	
Jennifer L. Reynaud, Washington, DC	-	
Jennifer L. Reynadd, Washington, De	, for respondent.	

MILLMAN, Special Master

DECISION¹

On June 17, 2011, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–10-34, alleging that Gardasil (human papillomavirus vaccine), DTaP vaccine, and Menactra (meningococcal vaccine) administered June 18, 2007 caused seizures 17 days later.

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

At the beginning of this litigation, counsel represented petitioner. During the first telephonic conference held on August 19, 2011, respondent's counsel requested that petitioner file an expert report in support of her allegations. The undersigned gave petitioner's counsel a deadline of October 18, 2011 within which to file an expert report.

On October 18, 2011, petitioner's counsel moved for an extension of time of 60 days within which to file an expert report. The undersigned granted petitioner's counsel's motion and set a new deadline for an expert report of December 19, 2011.

On December 19, 2011, petitioner's counsel moved for an extension of time of 45 days within which to file an expert report. The undersigned granted petitioner's counsel's motion and set a new deadline for an expert report of February 2, 2012.

On February 2, 2012, petitioner's counsel moved for an extension of time of 45 days within which to file an expert report. The undersigned granted petitioner's counsel's motion and set a new deadline for an expert report of March 19, 2012, stating this would be the last delay since the cumulative delay was 120 days.

On March 21, 2012, the undersigned held a telephonic status conference with the parties. Petitioner's counsel said he was seeking a new expert to review the case. The undersigned gave petitioner until May 18, 2012 to file an expert report.

On May 18, 2012, petitioner filed the expert report of Dr. Garrett C. Burris, a pediatric neurologist, as Exhibit 5. Dr. Burris wrote that Gardasil caused petitioner's seizures because literature says there have been seizures reported after administration of the vaccine. He gives no other basis, but provides an article and a textbook chapter in support. The first article (Exhibit 7), "Human Papillomavirus Vaccine Safety in Pediatric Patients: An Evaluation of the Vaccine Adverse Event Reporting System" By N.L. Borja-Hart, et al., 43 Ann Pharmacotherapy 356-59 (2009), describes reports of seizures after Gardasil vaccine from one to seven days later. (Petitioner's seizure onset was 17 days later.) The authors conclude at page 358 that they are unable to show any causality between the Gardasil vaccine and any of the serious events reviewed in this article. Thus, this article provides no support for petitioner's allegation that Gardasil caused her seizures. The textbook chapter (Exhibit 8), "Autoimmune Epilepsy" by S.R. Irani and B. Lange, in Diagnostic Criteria in Autoimmune Diseases (eds.) Y. Shoenfeld, et al., discusses a disease petitioner does not have. Her seizures have never been identified as autoimmune. The author of this chapter does not discuss vaccines. This chapter, too, provides no support for petitioner's allegation that Gardasil caused her seizures.

During a telephonic status conference held on May 31, 2012, respondent's counsel said she was familiar with an article Dr. Burris cited in his expert report but which petitioner did not file. Dr. Burris did not give the title or authors of the article, but stated that the <u>Journal of the American Medical Association</u> published it. 302 <u>JAMA</u> 750-57 (2009). Dr. Burris stated in his expert report that it concerns seizures after Gardasil, but respondent's counsel stated it concerns

fainting after receipt of Gardasil. Petitioner does not allege Gardasil caused her to faint. Petitioner's counsel said during the status conference that he would discuss the undersigned's concerns with Dr. Burris's report with Dr. Burris.

During a June 7, 2012 telephonic status conference, petitioner's counsel stated Dr. Burris requested additional time to consider the undersigned's concerns and counsel asked for two weeks to see if Dr. Burris wanted to do a supplemental report.

On June 21, 2012, the undersigned held a telephonic status conference during which petitioner's counsel stated that Dr. Burris said the literature does not support the time frame in petitioner's case. The protocols for the study in the article (Exhibit 7) did not go beyond two weeks. Petitioner's counsel wanted 60 days to file a supplemental expert report from Dr. Burris. In an order, the undersigned set a deadline for August 20, 2012 for the supplemental report, but petitioner's counsel was to file a status report on July 23, 2012 informing the undersigned if petitioner was proceeding with her case.

On July 23, 2012, petitioner's counsel moved to withdraw from the case. The undersigned granted this motion in an order dated July 25, 2012, enclosing a list of attorneys admitted to practice in the Vaccine Program for petitioner to review if she wanted to seek another attorney and requesting that petitioner contact the undersigned's law clerk to tell the law clerk if petitioner intended to proceed and, if she did, to set up a telephonic status conference.

On August 2, 2012, the undersigned issued an order setting a telephonic status conference with petitioner and respondent's counsel on August 15, 2012. Petitioner stated on that day that she was looking for another attorney, but had not found one. Another status conference was set for September 14, 2012 with petitioner's consent. Petitioner did not appear. She e-mailed the undersigned's law clerk to say she wanted more time to find an attorney. Another status conference was set for October 25, 2012 with petitioner's consent. Petitioner did not appear for this status conference.

On October 31, 2012, the undersigned issued an Order to Show Cause why this case should not be dismissed and gave petitioner until November 30, 2012 to reply to the Order to Show Cause. Petitioner has not replied to the Order to Show Cause.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" <u>i.e.</u>, "evidence in the form of scientific studies or expert medical testimony[.]"

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." <u>Grant</u>, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for Gardasil, she would not have seizures, but also that the vaccine was a substantial factor in causing her seizures. <u>Shyface v. Sec'y of HHS</u>, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Petitioner filed the expert report of Dr. Burris which is deficient in not fulfilling the three prongs of the Althen case. Dr. Burris does not proffer a persuasive medical theory causally connecting Gardasil and seizures (prong one). He does not provide a logical sequence of cause and effect showing that Gardasil was the cause of petitioner's seizures (prong two). And he does not prove that 17 days is an appropriate time interval between Gardasil vaccination and the onset of seizures to connote causation (prong three). Dr. Burris's only basis for his causation opinion is medical literature which does not support his opinion. The authors of the article about Gardasil say their study does not prove causation. Moreover, no seizures that they included in their study occurred further than seven days after vaccination. The authors of the textbook chapter which Dr. Burris cites discuss autoimmune epilepsy, but not vaccinations. Petitioner does not have autoimmune epilepsy. Dr. Burris never provided the JAMA article he said supports his opinion. This lack of filing makes ascertainment of the truth of his statement impossible. But respondent's counsel, who is familiar with the article, says it concerns fainting. The undersigned takes no position about what the JAMA article contains since petitioner never filed it. Dr. Burris's expert report does not constitute prima facie evidence that Gardasil vaccine caused petitioner's seizures.

Petitioner has not produced medical records or credible medical expert opinion to substantiate her allegations. The Vaccine Act does not permit the undersigned to rule in favor of petitioner based solely on her allegations unsupported by medical records or credible medical opinion. 42 U.S.C. § 300aa-13(a)(1).

This petition is **DISMISSED** for failure to make a prima facie case and failure to prosecute.

CONCLUSION

This petition is DISMISSED . In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith. ²		
IT IS SO ORDERED.		
DATE	Laura D. Millman Special Master	

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.